Remarks

The specification and Claims 1, 3-5, 8 and 9 have been amended with the details set forth in Attachment I (Version with Markings to Show Changes Made). Non-elected Claims 10-35 have been cancelled without prejudice to the filing of a divisional application covering this claimed subject matter. New Claims 36-43 have been added.

Restriction Requirement

The restriction between Claims 1-9 and 10-35 has been made Final. Non-elected Claims 10-35 have been cancelled.

Drawing Objections

The objections to the drawings as set forth in paragraph 4 of the Office Action are not understood. 37 CFR 1.84(p)(4) does not require each embodiment illustrated to contain the same reference numeral for similar components. For example, elements 12 and 33 are microbeads but such may not be identical. Thus, this objection is deemed to be improper and should be withdrawn.

The objections set forth in paragraph 5 of the Office Action have been overcome by amendments to the specification or changes in the drawing Figure 8.

As to the objection in paragraph 6 of the Office Action, reference to d' and e' have been added to the description of Figures 5 and 6. These numerals do not appear in Figures 11B or 12B, as inferred by the Examiner.

The 35 USC 112 Rejection

Claims 1-9 are rejected under 35 USC 112, second paragraph, as being indefinite. Certain of the objections have been overcome by the amendments to the claims. However, specific "attaching methods" need not be set forth in a claim. It is

submitted that each objection has been overcome, and this rejection should be withdrawn.

The 35 USC 103 Rejections

Claims 1-3, 5-7, and 9 are rejected under 35 USC 103(a) as unpatentable over Pyle et al; and Claims 1, 4-6, and 8-9 are rejected under 35 USC 103(a) as unpatentable over Marshall in view of Okusa et al. Claim 1 sets forth "attaching the microbeads to a disposable capture substrate..." and inserting the substrate an optical detection system...". None of the three applied references teach or suggest these claimed features. Thus, these rejections should be withdrawn.

Conclusion

In view of the amendments to the specification and claims, cancellation of the non-elected claims, the changes in Figure 8, and the foregoing comments, each objection and rejection is believed to have been overcome. Thus, this application is in condition for allowances based on Claims 1-9 and new Claims 36-43.

Respectfully submitted,

Dated: 10-2-02

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Enclosures:
Attachment I
Photocopy of Figure 8

Attachment I
S.N. 09/880,515
Version with Markings to Show Changes Made

In The Specification:

Page 9, paragraph "**[0029]**", rewrite to read:

[0029] Figure 8 illustrates a top view [few] of an embodiment of the handheld detection device, with sections removed to illustrate the interior thereof.

Page 11, paragraph "**[0038]**", rewrite to read:

[0038] The process of the portable pathogen detection system is illustrated in Figure 4-6 and 7A-7C. Sample 10 is added to a cuvet 11 containing optically encoded microbeads 12. Each microbead 12 contains a capture ligand a, b, and c and bioagent-specific antibodies d, e, and f. Each microbead, in addition to the standard sample capture assay, contains special attachment sites. The cuvet 11 is then placed in a mixing holder as indicated by arrow 13 and as shown in Figure 5 (see Figure 8 and 9), providing time for the targeted biological sample to adequately bind the microbeads, as indicated at d' and e'. Then, as indicated by arrow 14, fluorescent reporter labeled antibodies 15 are added to cuvet 11 , see Figure 6, that attach to the microbead bound sample 12^1. Then, as indicated by arrow 16, a disposable capture substrate 17 containing a patterned array of attachment sites 18, see Figure 7B, is inserted as indicated by arrow 19, see Figure 7A, into the cuvet 11. Each attachment site 18 of the array on the disposable capture substrate 17, as seen in Figure 7B, is designed to capture a single bead 12 or 12^1, with the spatial distance between each site 18 determined by the resolution of the optical detections systems. After the microbeads 12 and 12^1 are attached to the sites 18 of substrate 17, as shown in Figure 7C, the substrate 17 is removed from cuvet 11 [18] located in the mixing holder and placed in a wash receptacle. This wash step improves the sensitivity of the detection process by

removing from the disposable capture substrate surface all unbound biological constituents and reducing the background solution florescence. Finally, the disposable microbead capture array is placed in a detection shot or reaction chamber, see Figures 8 and 9, where the microbeads are optically decoded for proper identification and measurement of target biological molecules.

Page 12, paragraph "**[0039]**", rewrite to read:

[0039] The principal components of the portable pathogen detection system as illustrated in the embodiment of Figures 8 and 9, are: 1) optically encoded microbead reagents (bead pack), 2) mixing chambers located in a vibration unit, 3) disposable substrate with ordered microbead attachment array, and 4) optical analyzers each principal component being described in detail below. As shown, the portable pathogen detection system of Figures 8 and 9 is a handheld device and comprises a casing or housing 20 which can be held in a human hand 21, the housing 20 including a plurality of mixing chambers 22 within which bead packs 23, see Figure 9, are located within a vibration or mixing unit 24, an opening 25 within which is located one or more disposable capture substrates 26 for storage purposes prior to insertion thereof into a bead pack 23, see Figure 9, a reaction chamber 27 into which a disposable capture substrate 26 is finally positioned for at least washing thereof, see Figure 9, and an analyzer generally indicated at 28 having indicators generally indicated at 29 and [30] 29' on the face of housing 20. The above mentioned four (4) principle components are further described as follows:

In The Claims:

Claims 1, 3-5, 8, and 9, amend to read as follows:

1. (Amended) A method for pathogen detection comprising:

containing optically encoded microbeads,

adding a sample and capture ligand to the contained microbeads,

placing the contained microbeads in a mixing holder for sufficient time for a [the] targeted biological sample to adequately bind the microbeads,

adding fluorescent labeled antibodies for attachment to the microbead bound sample,

attaching the microbeads to a disposable capture substrate containing an array of attachment sites for attaching the microbeads thereto,

washing the substrate and attached microbeads, and

inserting the substrate into an optical detection system for optically decoding the microbeads for identification and measurement of the target biological sample [molecules].

3. (Amended) The method of Claim 1, [wherein] additionally including vibrating the mixing holder [is vibrated] during the time the contained microbeads are placed therein.

4. (Amended) The method of Claim 1 [wherein] additionally including designing each of pattern array of attachment sites on a [the] dipstick [is designed] to capture a single microbead.

5. (Amended) The method of Claim 1, [wherein] additionally including locating the patterned array of attachment sites on the substrate [are located] at a spatial distance between each as determined by a [the] resolution of the optical detection system.

8. (Amended) The method of Claim 1, [wherein] additionally including providing each microbead [is of] with a different color and containing [contains] a substrate capture point and an [a unique] assay.

9. (Amended) The method of Claim 1, [wherein] additionally including processing each microbead [is processed] to contain a capture ligand, and a bioagent-specific antibody, and with certain of the microbeads also having a target species bound thereto, and a fluorescent labeled antibody attached thereto.

Claims 10-35 have been cancelled.

Claims 36-43 have been added.